SEP 2 2003 K032545

8 510(k) CUJ Summery/ Statement

510(k) CUJ Summery/ Statement for LS-3000X, LS-1800XG (Med Light X 180) and LS-2500H (Med Light H 250)

I Submitter

MGB Endoskopische Geräte GmbH Berlin
Schwarzschildstraße 6
12489 Berlin
Germany

II Device Names

1.	Classification Name:	Accessory to an Endoscope
2.	Common or Usual Name:	Endoscopic Light Source (Xenon Light Source)
3.	Proprietary Name:	Endoscopic Light Source LS-3000X, LS-1800 XG and LS-2500H for MGB brand Med Light X 180 and Med light H 250 for LAWTON brand

III Classification:

Class II. This device is described in21 C.F.R.§876.1500: The product code for the device is GCT.

IV Predicate Device:

name/ manufacturer:	World of Medicine Lemke GmbH
labeling:	For LS-1800XG (Med Light X 180): Endoscopic Light source XL180/L3 For LS-3000X :Endoscopic Light source XL300/L5 For LS-2500H (Med Light H 250): Endoscopic Light source XL202/L3

V Intended Use:

The light Sources LS-3000X, LS-1800XG (Med Light X180), LS-2500H (Med Light H250) provide illumination for fiberoptic endoscopy to gastroenterological and urological cavities, hollow organs and canals.

VI Device Describtion

The Endoscopic Light Source LS-300X uses a 300W xenon lamp to provides illumination during endoscopic diagnostic and surgical procedures through a fiber optic cable, which is connected to the device. Brightness can be adjusted manually. The color temperature is approximately 5600°K and the lamp life is approximately 500 hours.

The Endoscopic Light Source LS-1800X (Med Light X 180) uses a 180W xenon lamp to provides illumination during endoscopic diagnostic and surgical procedures through a fiber

optic cable, which is connected to the device. Brightness can be adjusted manually. The color temperature is approximately 6000°K and the lamp life is approximately 500 hours.

The Endoscopic Light Source LS-2500H (Med Light H 250) uses two 250W halogen lamps to provides illumination during endoscopic diagnostic and surgical procedures through a fiber optic cable, which is connected to the device. Brightness can be adjusted manually. The color temperature is approximately 3400°K and the lamp life is approximately 50 hours.

VII Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the predicate device. The new devices have no diminished safety or effectiveness.
The LS-3000X is similar in design and technological characteristics to the Endoscopic Light Source XL300/L5 (K021717), the LS-1800XG (Med Light X 180) is similar in design and technological characteristics to the Endoscopic Light Source XL180/L3 (K023468) and the LS-2500H (Med Light H 250) is similar in design and technological characteristics to the Endoscopic Light Source XL202/L3 (K20889), manufactured by World of Medicine Lemke GmbH.

Both the LS-3000X, LS-1800XG (Med Light X 180), LS-2500H (Med Light H 250) and the predicate device are intended to provide illumination of body cavities, hollow organs and canals during endoscopic diagnostic and surgical procedures. In addition, both devices are designed to be used the same lamps.

The differences between the LS-3000X, LS-1800X (Med Light X 180), LS-2500H (Med Light H 250) and the predicate devices are minor and raise no new questions of safety and effectiveness. Accordingly, MGB Endoskopische Geraete GmbH Berlin believes that the Endoscopic Light sources LS-3000X, LS-1800X (Med Light X 180), LS-2500H (Med Light H 250) are substantially equivalent to the predicate devices currently on the market.

VIII Performance Data

The Endoscopic Light sources LS-3000X, LS-1800X (Med Light X 180), LS-2500H (Med Light H 250) will comply with the International Standard IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18 and will conform to the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2003

MBG Endoskopische Geräte GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K032545
Trade/Device Name: LS-3000S; LS-1800XG/Med Light X 180; LS-2500H/Med Light H 250
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FET
Dated: August 1, 2003
Received: August 18, 2003

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032545

3 Statement of Indications for use

Applicant: MGB Endoskopische Geräte GmbH Berlin

510(k) Number: K032545

Device Name: Endoscopic Light Source (Xenon Light Source)

LS-1800XG (for MGB brand), Med Light X 180 (for Lawton brand)
LS-3000X (for MGB brand)
LS-2500H (for MGB brand), Med Light H 250 (for Lawton brand)

Indications for Use:

Light Sources LS-1800XG (Med Light X180), LS-3000X, LS-2500H (Med Light H250) provide illumination for fiberoptic endoscopy to gastroenterological and urological cavities, hollow organs and canals.

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 C.F.R. $ 801.109)

Prescription Use ✓

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032545